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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,805	12/04/2003	Spiridon Spireas	MPCI-0135	6832

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EXAMINER	
SOROUSH, ALI	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,805	SPIREAS, SPIRIDON	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *1-30,32-53 and 55-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,54 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Receipt

Applicant's response filed 05/07/2007 to the Office Action mailed on 04/05/2007 is acknowledged.

Status of the Claims

Claims 1-30, 32-53, and 55-69 are withdrawn by the applicant and claim 70 was amended. Therefore, claims 31, 54, and 70 are currently under examination for patentability.

Election/Restrictions

Applicant's election of Group III (claims 31, 54, and 70) with traverse is acknowledged.

Applicant's election with traverse of the method of treatment of a cardiovascular disorder with an ACE inhibitor formulation in the reply filed on 05/07/2007 is acknowledged. The traversal is on the ground(s) that Groups I, II, and III have been noted by the examiner as being in the same class and subclasses and therefore would not place an undue burden on the examiner to search all the claims together. This is not found persuasive because although the examiner concedes that the inventions of the Groups are indeed classified together, however the search of the different groups would require the examiner to perform a different search query and further perform searches in a variety of different electronic databases.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 54, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 54, and 70 recite, "having a bio/storage stability ratio". It is not clear from the specification and/or the claims what the definition of bio/storage stability ratio is. Further this is not a term commonly known to one of ordinary skill in the art. Therefore, these claims fail particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 further recites, "hydrolytic breakdown products". It is not clear from the specification and/or the claims what constitutes a breakdown product and what does not constitute a breakdown product in an ACE-inhibitor formulation used to treat cardiovascular diseases. Therefore, the claim fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70, recites, "A method, comprising administering". It is not clear what method applicant is claiming. The claim only recites active steps but does not state what the active steps are intended to accomplish. Therefore, the claim fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 is interpreted to read on a method of treating a cardiovascular disorder for the purpose of examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 54, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (US Patent 4743450, Published 05/10/1998).

Harris et al. teaches, "a pharmaceutical composition which contains: (a) a drug component which comprises an ACE inhibitor which is susceptible to cyclization, hydrolysis, and/or discoloration. (b) an amount of stabilizer(s) suitable to retard cyclization and/or hydrolysis." (See column 1, Lines 45-51). "Certain ACE (Angiotensin Coverting Enzymes) inhibitors, which are useful as antihypertensives, are susceptible to certain types of degradation. Specifically quinapril and structurally-related drugs degrade via (1) cyclization via internal nuceophilic attack to form substituted diketopiperazines, (2) hydrolysis of the side chain ester group, and (3) oxidation to form products having often unwanted coloration." (See column 1, Lines 5-12). Harris et al teach in a particular preferred embodiment a formulation is made comprising: 43.4 mg Quinapril hydrochloride, 250.0 mg magnesium carbonate, 66.6 mg lactose, 20.0 mg gelatin, 16.0 mg polyplasdone, and 40 mg magnesium stearate. (See column 5, Example B). Stabality testing performed at 60°C for one month gave the following

results: 98.1% Quinapril, 0.6% Diketopiperazine, and 1.2% hydrolysis product. (See column 5, example E). Harris et al. further teach that such formulations have greater storage stability and are rendered more suitable for use in drug combinations. (See column 1, Lines 36-38). With regard to the bio/storage stability ratio it is the examiners position that instant invention would be inherent to the formulation of Harris et al. Since the formulation is not structurally distinguishable from the instant formulation it would be expected that bio/storage stability would also be the same. With regard to the limitation recited in claim 70, "after storage at 25°C and ambient humidity for 12 months" since the composition taught by Harris et al. is not structurally distinguishable from the instant formulation it would be expected that the formulation of Harris et al. would also have the same degradation product concentrations under the conditions instantly claimed. Therefore, without a showing of unexpected results, the instant method of treatment is anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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